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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,475	02/06/2002	Roger A. Stern	16904-753	3000

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[REDACTED] EXAMINER

PEFFLEY, MICHAEL F

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

3739

DATE MAILED: 07/30/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/072,475	Applicant(s) STERN ET AL.
	Examiner Michael Peffley	Art Unit 3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 February 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10, 14-18, 21-23, 25, 28-39, 43-47, 50-52, 57-67, 71-75, 78-80 and 84 is/are rejected.
- 7) Claim(s) 11-13, 19, 20, 24, 26, 26, 40-42, 48, 49, 53-55, 68-70, 76, 77 and 81-83 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 34 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims all lack proper antecedent basis for "the electrode assembly".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-10, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Eggers ('314).

Eggers provides a device which comprises a handpiece (13) having an insert (11) detachably coupled to the handpiece. The insert includes an RF electrode (12) which is comprised of a dielectric portion and conductive portions (Figure 3A-4B). Eggers et al also disclose providing a cooling fluid from the handpiece through the insert and to the electrode. A valve (17) is located in the handle assembly. The examiner maintains that the fluid delivery system is capable (i.e. "configured to") deliver a controllable amount of fluid in pulses through operation of the valve. It is noted that the

distal exit of the insert may be interpreted to be both a nozzle for the fluid delivery and a vent.

Claims 1, 14, 25, 30, 43, 56-68, 71 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Pomeranz et al ('579).

The Pomeranz et al device comprises a handpiece (271) with an insert (32) detachably coupled to the handpiece. The insert includes a plurality of RF electrodes arranged on a flex-circuit (col. 19, lines 10-17), the flex circuit including a dielectric portion with a plurality of leads or traces.

Claims 1, 17, 18, 21-23, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Negus et al ('848).

Negus et al disclose an apparatus which includes a handpiece (130,140) into which an insert (i.e. catheter) is detachably coupled. The insert includes an RF electrode at the distal end, as well as a sensor means to sense the force exerted by the tip on tissue (col. 2, lines 46-57). The sensor is disclosed as being capable of sensing various parameters including force, contact with tissue, channel depth, etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 45 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teaching of Eggers ('314).

As addressed previously, Eggers provides a device comprising a handpiece and a detachable insert coupled to the handpiece. There is a valve means (17) located on the handpiece for controlling the flow of fluid through the handpiece and the insert and to the electrode. Eggers discloses a simple push valve, and fails to specifically disclose a solenoid valve. The examiner maintains that the use of solenoids as valves is generally well known and would be an obvious substitution for the Eggers push valve to serve the same purpose.

To have used any well known type of valve (e.g. solenoid valve) to control the flow of fluid in the Eggers device would have been an obvious modification for one of ordinary skill in the art at the time of the invention.

Claims 31-33, 35-39, 44, 59-61, 63-67 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pomeranz et al ('579) in view of the teaching of Eggers ('314).

As addressed previously, Pomeranz et al disclose a device comprising a handpiece and a detachable insert coupled to the handpiece having a flex circuit for an electrode. Pomeranz et al also teach that a fluid may be provided through the insert to the electrodes (col. 12, lines 57-67). There is no specific teaching of providing the cooling medium through the handpiece housing. Rather, the fluid is introduced through a port (116b) located just distal to the handpiece housing.

Eggers teaches an analogous RF treatment device which provides a fluid to an RF electrode. The device includes a handpiece with a means to control the delivery of fluid (i.e. a valve) to the insert and electrode located on the housing. As asserted previously, the examiner maintains that such a fluid control system inherently is capable of providing a controlled amount of fluid in a pulsed manner through actuation of the valve.

To have provided the Pomeranz et al device with a fluid control means (i.e. valve) located on the handpiece housing so as to control the delivery of fluid through the insert and to the electrodes would have been an obvious modification for one of ordinary skill in the art.

Claims 30, 46, 47, 50-52, 56, 58, 74, 75, 78-80 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negus et al ('848) in view of the teaching of Swanson et al ('650).

Negus et al has been addressed previously. Negus et al disclose a catheter (i.e. insert) which includes one or more electrodes for the treatment of tissue. Negus et al fail to specifically disclose the use of a flex circuit for forming the electrodes on the catheter.

Swanson et al also disclose an RF catheter having electrodes on the distal end for treating tissue. In particular, Swanson et al teach that it is known to form the electrodes in a variety of ways, including using a flexible circuit to form the electrodes (col. 7, lines 7-30).

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To have formed the Negus et al electrodes as a flex circuit located on the catheter body as an alternative to the deposited electrodes would have been an obvious design consideration for one of ordinary skill in the art, particularly since Swanson et al teach that flex circuit electrodes are known alternatives to metallic deposited electrodes on RF catheters.

Allowable Subject Matter

Claims 11-13, 19, 20, 24, 26, 27, 40-42, 48, 49, 53-55, 68-70, 76, 77 and 81-83 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 5, 34 and 62 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

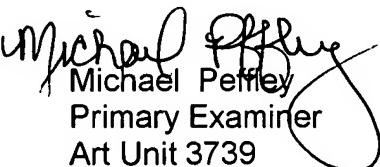
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Philips ('176) and Desai ('503) disclose electrosurgical systems which include a handpiece with a plurality of interchangeable inserts for use therewith. Hall et al ('699) discloses an electrode assembly which includes a plurality of cooled electrodes. Simada ('466) and Muller et al ('426) disclose a force sensor used in conjunction with a laser handpiece device.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
July 25, 2003